#2

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 380 668 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent: 27.12.1996 Bulletin 1996/52

(21) Application number: 88908753.2

(22) Date of filing: 07.10.1988

(51) Int. Cl.^{6}: A61B 17/00

(86) International application number: PCT/JP88/01029

(87) International publication number: WO 89/03197 (20.04.1989 Gazette 1989/09)

(54) INSTRUMENT AND APPARATUS FOR SECURING INNER DIAMETER OF LUMEN OF TUBULAR ORGAN

INSTRUMENT UND VORRICHTUNG ZUM AUFRECHTERHALTEN DES INNEREN LUMENDURCHMESSERS EINES SCHLAUCHFÖRMIGEN ORGANS

INSTRUMENT ET DISPOSITIF DE MAINTIEN DU DIAMETRE INTERNE D'UN PASSAGE DANS UN ORGANE TUBULAIRE

(84) Designated Contracting States: BE DE FR GB IT NL SE

(30) Priority: 08.10.1987 JP 252457/87
02.11.1987 JP 275655/87

(43) Date of publication of application: 08.08.1990 Bulletin 1990/32

(73) Proprietor: TERUMO KABUSHIKI KAISHA
Tokyo 151 (JP)

(72) Inventors:
- HARADA, Fumiaki
Fuji-shi Shizuoka 417 (JP)
- ISHIDA, Toshinobu
Fuji-shi Shizuoka 417 (JP)

(74) Representative: Casalonga, Axel et al
BUREAU D.A. CASALONGA - JOSSE
Morassistrasse 8
80469 München (DE)

(56) References cited:
FR-A- 2 248 303
JP-A- 6 282 975
JP-B- 0 616 655
US-A- 4 503 569
US-A- 4 681 110
JP-A- 6 055 964
JP-A- 6 282 976
US-A- 3 923 065
US-A- 4 665 918

Printed by Rank Xerox (UK) Business Services
2.13.10/3.4

Description

The present invention relates to an expansion unit for expanding the lumen of tubular organs, such as for example, a blood vessel, a digestive tube, an air tube, etc., and an apparatus for indwelling and withdrawing the expansion unit.

Conventionally, expansion units (stents) have been proposed to maintain the inside diameter of the lumen of a tubular organ so as to prevent, for example, a coronary artery from relapsing into a constricted state after it has been dilated and indwelt by an angiectasia catheter.

A conventional expansion unit, as disclosed in Japanese Patent Examined Publication No. 61-6655, uses a unidirectional shape memory alloy made of Ti-Ni binary alloys. A tube, previously having almost the same inside measurement as that of a normal blood vessel, is shaped before its shape is memorized in the shape memory alloy. After the outside diameter of the shape memory alloy is reduced for easy introduction into a desired location of a blood vessel, the alloy is heated in warm water and the like to be expanded and recovered so as to return to the memorized shape.

Document US-A-4 503 569 discloses a tubular organ expansion apparatus for indwelling a tubular expansion unit in a lumen of a tubular body organ. The expansion unit is made of a shape memory alloy and in particular is a coil wire made of Nitinol® alloy. The wire is heated until its crystal structure assumes its high temperature austenite configuration also known as the beta or parent phase. Next, the wire is cooled so that the atoms in the metal rearrange themselves into a crystal structure known as martensite. The coil wire will revert to the large diameter configuration when heated to a temperature at which the crystal structure reverts to the parent phase and will retain this shape unless it is cooled below a temperature at which martensite transformation occurs. Such an alloy is a unidirectional shape memory alloy.

(A) For example, in the work of indwelling the above-described conventional expansion units into a desired location of the blood vessel, the expansion unit is attached to the distal end portion of a catheter and inserted to the desired location in a blood vessel using an X-ray transmission. It is therefore desirable to provide high contrast for X-rays when inserting and indwelling the expansion unit in the desired location of tubular organs, such as a blood vessel.

However, the expansion unit is thinly built because of its inherent functions, such as maintaining the inside diameter of a blood vessel after being indwelt in the blood vessel to keep a stable blood flow. For which reason, poor contrast is provided for the unit.

Further, it is difficult to say from the viewpoint of material that a shape memory alloy, for instance, Ti-Ni binary alloy, comprising the expansion unit provides high contrast.

(B) Also, in the course of indwelling the above-described conventional expansi n unit made of the unidirectional shape memory alloy into a desired location in a blood vessel, as a normal practice, a guiding catheter is first dwelt in the vessel and then the expansion unit slided toward a desired location, while simultaneously passing through the inside of the guiding catheter. In this case, however, since the expansion unit is slided through the narrow inside of the guiding catheter without a protective wrap around it, the expansion unit may get caught or deformed midway through. Furthermore, because the guiding catheter is generally very rigid, it cannot travel through a bend in the periphery in the blood vessel. Therefore, when a desired location for indwelling is farther away from the bend, the expansion unit may get caught and deformed midway through because the unit, without a protective wrap around it, together with the catheter, slides inside the vessel.

The expansion unit, which has already been proposed by the inventors of this invention, made of bidirectional shape memory alloy, is epoch-making as an expansion unit capable of changing indwelling positions and withdrawal. That is, the expansion unit is characterized in that a bidirectional shape memory alloy, in which two reversible memory shapes, high and low temperature sides, appear reversibly on the borderline of a certain transformation point, is expanded diametrically to obtain the inside measurement of a blood vessel and the like at around body temperature, and is capable of travelling inside of the blood vessel by being contracted diametrically at or below body temperature. However, the above-described expansion unit slides through the narrow inside of the guiding catheter without a protective wrap around it. As a result, the expansion unit may get caught and deformed midway through. Moreover, while the expansion unit slides inside of the guiding catheter, a large amount of cooling water must be fed to keep the expansion unit contracted diametrically. Further, as is the same with a unidirectional shape memory alloy, the guiding catheter is too rigid to travel through a bend in the periphery in a blood vessel. Therefore, when the expansion unit is inserted after the guiding catheter is removed or when a desired location for indwelling is farther away from the bend, the expansion unit may get caught and deformed midway through because the unit equipped with the catheter slides through the inside of the blood vessel without a protective wrap around it, and a large amount of cooling water must be fed to keep the expansion unit contracted diametrically.

It is therefore an object of this invention to provide an expansion unit made of a bidirectional shape memory alloy, which allows high contrast for X-rays, to insert and indwell the expansion unit into a desired location of tubular organ.

It is another object of this invention to make it possible for the expansion unit to travel smoothly and readily through the tubular organ.

According t th invention, th re is provided a tubular-organ expansion apparatus for indwelling a tubular expansion unit in a lumen of a tubular body organ comprising the combination of:

- a tubular organ expansion unit consisting of a cylindrical body of a given contrast made of a bidirectional shape memory alloy having a given density which is insertable into a tubular body organ and capable of maintaining an inside diameter of a lumen of the tubular body organ, said cylindrical body being capable of reversibly achieve an unexpanded state of a given radial dimension and outside diameter in a first temperature range below body temperature and an expanded state of an increased given radial dimension and outside diameter in a second temperature range around body temperature;
- a catheter including a base portion having an outside diameter, a distal end portion having an outside diameter, an outside portion having an outside diameter and a tubular-organ expansion unit attaching portion having a periphery in the vicinity of said distal end portion for attaching said tubular-organ expansion unit to said catheter; and
- a catheter sheath having first and second open end portions sheathing said tubular-organ expansion unit when said tubular organ expansion unit is attached to said tubular organ expansion unit attaching portion, said catheter sheath comprising a flexible catheter tube having an inside diameter smaller than the outside diameter of the tubular-organ expansion unit in its expanded state but larger than the outside diameter of the tubular-organ expansion unit in its unexpanded state, said tubular-organ expansion unit being fixed to the inside of said sheath when the combination of said tubular-organ expansion unit, said catheter and said sheath is held at a temperature within said second temperature range so that said combination can be introduced as a whole in the vicinity of the indwelling location of said tubular-organ expansion unit.

In an embodiment of the present invention, the cylindrical body of the tubular-organ expansion unit is coil-like.

In another embodiment of the present invention, the cylindrical body has a cross section of helical shape.

In another embodiment of the present invention, the cylindrical body is slit lengthwise.

In another embodiment of the present invention, the cylindrical body is mesh-like.

In another embodiment of the present invention, the cylindrical body is made by thin woven-shaped wires.

In another embodiment of the present invention, the cylindrical body comprises metals of a higher density than the bidirectional shape memory alloy plated thereon.

In another embodiment of the present invention, the cylindrical body comprises metals of a higher density than the bidirectional shape memory alloy, wound or pressed thereon.

An expansion unit made of bidirectional shape memory alloy according to this invention is expanded by ① external force or ② the effect of recovery in relation to a memorized shape based on temperature differences, to obtain the inside measurement of the lumen of tubular organs after being inserted under contrast of X-ray transmission into a desired location in tubular organs such as a blood vessel.

Thus, the expansion unit provides high contrast for X-rays by plating or pressing at least part of the cylindrical body of the expansion unit with metals whose density is higher than that of the bidirectional shape memory alloys. Accordingly, the expansion unit inserted into a tubular organ provides contrast for X-rays and is inserted and indwelt in the desired location of the tubular organ.

As regards the bidirectional shape memory alloy used for the expansion unit according to this invention, for example, Ti-Ni binary alloy (composition: Ni atomic percent 50-53, preferably, 50-51, transformation starting point: As 30-45°C, M_s 10-30°C) is preferable.

Also, in this invention, such metals as Cu, Ag, Pt and Au whose density is higher than that of the bidirectional shape memory alloy are preferably used for increasing X-rays contrast.

As previously stated, the tubular-organ expansion apparatus for indwelling the tubular-organ expansion unit in the lumen of a tubular organ, comprises a unit having a substantially tubular body made of a bidirectional shape memory alloy and capable of changing its radial dimension in response to a change in temperature, a catheter where the tubular-organ expansion unit can be attached to the periphery of a unit-attaching portion in the vicinity of the distal end portion of the catheter, and a catheter sheath with both ends thereof opened, into which the attached catheter with the tubular-organ expansion unit, can be sheathed.

In a preferred embodiment of the present invention, the catheter is provided with a passageway extending from the base portion thereof to at least a location in the vicinity of the distal end portion thereof, and with side pores or slit-like communication apertures on the unit-attaching portion in the vicinity of the distal end portion thereof for providing communication between the passageway and the outside of the catheter.

Preferably, the outside diameter of the base portion and the distal end portion of the catheter, or the outside diameter of the base of the catheter, are larger than that of the tubular-organ expansion unit attached to the unit-attaching portion.

In another preferred embodiment of the present invention, th catheter is provided with the lumen of the

catheter extending from the base portion thereof to at least a location in the vicinity of the distal end portion thereof, and with a hollow hub on th bas portion for communicating with the lumen of the catheter, th passageway being defined by the lumen of the catheter and the lumen of the hub.

The hub preferably comprises a branch hub having two ports and one of the ports being provided with a check valve.

The catheter may also preferably be provided with at least one X-ray non-transmission marker in the vicinity of the distal portion thereof.

An X-ray non-transmission material may be mixed within the material of the catheter sheath, or the catheter sheath may be provided with at least one X-ray non-transmission marker in the vicinity of the distal end portion thereof.

The catheter sheath is preferably constructed with the lumen of the sheath extending to both distal end portions thereof and with a hollow hub, having a check valve, at the base thereof for communicating with the lumen of the sheath.

According to a further embodiment of the invention, the inside diameter of the catheter sheath is smaller than the outside diameter of the tubular-organ expansion unit, whereby with both ends of the catheter sheath opened, the attached contracted tubular-organ expansion unit, can be sheathed.

Preferably, the catheter has the same outside diameter as the unit-attaching portion in the vicinity of the distal end portion thereof, which is equal to or slightly larger than the inside diameter of the tubular-organ expansion unit when the unit is contracted, and is capable of attaching the tubular-organ expansion unit to itself at substantially below body temperature.

Preferably, the outside diameter of a base portion and a distal end portion of the catheter, or the outside diameter of the base portion of the catheter, are larger than that of the tubular-organ expansion unit attached to the unit-attaching portion.

In the present invention, when the expansion unit is made of a bidirectional shape memory alloy, in an embodiment, a substantially coil-like or mesh-like cylindrical expansion unit, having an outside diameter, almost equal to or shorter than the lumen of a tubular organ for the unit to be indwelt, which is memorized substantially below body temperature, is utilized. In the expansion unit made of the bidirectional shape memory alloy, the outside diameter, which is substantially equal to or somewhat longer than the inside diameter of a tubular organ for the unit to be expanded and indwelt at around body temperature, is memorized. While the expansion unit is attached to the catheter, the unit is sheathed into a catheter sheath. The expansion unit is readily indwelt in and withdrawn from the desired location of the tubular organ directly or with the aid of the guiding catheter by means of the combination of the catheter and the catheter sheath.

That is, a guide wire is inserted by a known technique into the tubular organ where the expansi n unit is to rest, and then, along the guide wire, the expansion unit is readily inserted into the desired location of th tubular organ directly or with the aid of the guiding catheter by means of the combination of the catheter and the catheter sheath into the tubular organ. According to this invention, at this stage, because of the catheter sheath, the expansion unit, while it is being attached to the catheter, is firmly maintained in the sheath. Therefore, a large amount of cooling water is not required for winding the expansion unit around the catheter tightly so as to keep the inside diameter contracted. The patient's discomfort is thus reduced. Because of the catheter sheath, the expansion unit is not directly exposed to the guiding catheter or the tubular organ so that the unit does not get caught or deformed midway through. Furthermore, because the catheter sheath is flexible, it can easily slide, along with the expansion unit and the catheter, through the bend of a blood vessel.

The expansion unit inserted according to the above-described procedures is supplied with cooling water from the catheter sheath and/or the catheter to be wound around the catheter. Under this condition, after the unit is projected out of the catheter sheath, the supply of the cooling water is stopped. As a result, the expansion unit is heated and expanded by body temperature, and indwelt in the desired location.

Moreover, the withdrawal of the expansion unit thus indwelt in the desired location is performed according to the following procedures. The guide wire is first passed the location where the expansion unit is indwelt and along with this wire, the catheter, together with the catheter sheath, is inserted into the indwelling location. The distal end portion of the catheter is then projected out of the catheter sheath. The cooling water is fed from the catheter and/or catheter sheath for winding the expansion unit around the location where the unit is to be attached so as to contract the inside diameter of the unit. The wound expansion unit is withdrawn together with the catheter into the catheter sheath. In this case, a small amount of cooling water is sufficient. Further, once the expansion unit is pulled into the catheter sheath, it is certainly withdrawn without being caught or deformed midway through.

In a preferred embodiment in accordance with this invention, the catheter is provided with a passageway extending from its base portion to at least the location in the vicinity of the distal end portion and with communication apertures, which connect the passageway and the surface of the end where the expansion unit is to be attached. When the expansion unit, made of the above-described bidirectional shape memory alloy, is inserted or withdrawn, the cooling water may be fed from the communication apertures.

In this invention, the bidirectional shape memory alloy means the alloy where previously memorized shapes at high and low temperatures on the borderline of a certain transformation point appear reversibly according to changes in temperature.

As regards shape memory alloy used for the expansion unit according to this invention, for example, Ti-Ni binary alloy (composition: Ni atomic percent 50 - 53, preferably, 50 - 51, transformation starting point : As 30 - 45°C, Ms : 10 - 30°C) is preferable.

The indwelling of a tubular-organ expansion unit, made of a bidirectional shape memory alloy which changes diametrically in size in response to a change in temperature, into the lumen of a tubular-organ will now be explained. The tubular-organ expansion unit is attached to the periphery of the unit-attaching portion arranged in the vicinity of the distal end portion of the catheter. Thereafter, the combination of the catheter with the attached tubular-organ expansion unit is sheathed within the catheter sheath having both ends opened, and the whole is then inserted into a desired location of the tubular organ. The catheter and the tubular-organ expansion unit are projected out of the catheter sheath and the tubular-organ expansion unit is expanded by heat of the body for indwelling into the desired location.

Withdrawal of the indwelled tubular-organ expansion unit will now be explained. After the combination of the catheter and the catheter sheath is inserted into a location where the tubular-organ expansion unit is to be indwelt, the distal end portion of the catheter is projected out of the catheter sheath, the tubular-organ expansion unit then being reduced in size by the feeding of cooling water from the catheter sheath and/or the catheter in order to be wound around the unit-attaching portion of said catheter, and the wound tubular-organ expansion unit, together with the catheter, is withdrawn inside the catheter sheath. The combination of the catheter with the attached tubular-organ expansion unit and the catheter sheath having both ends opened, into which the catheter is sheathed, may also be inserted, through the lumen of a guiding catheter already indwelt in the tubular organ, into a desired location of the tubular organ. The catheter and the tubular-organ expansion unit are projected out of the catheter sheath and the tubular-organ expansion unit is expanded by heat of the body for indwelling into the desired location.

Similarly the combination of the catheter and the catheter sheath may be, through the lumen of a guiding catheter already indwelt in the tubular-organ, inserted into a location where the tubular-organ expansion unit has already been indwelt. The distal end portion of the catheter is projected out of the catheter sheath, the tubular-organ expansion unit then being reduced in size by the feeding of cooling water from the catheter sheath and/or the catheter in order to be wound around the unit-attaching portion of the catheter, and the wound tubular-organ expansion unit, together with the catheter, is withdrawn inside the catheter sheath.

FIG. 1(A), (B) is a side view showing an expansion unit of a first embodiment according to the present invention;

FIG. 2 (A), (B) is a perspective view showing th expansion unit of a second embodiment in accordance with this invention;

FIG. 3 (A), (B) is a perspective view depicting the expansion unit of a third embodiment according to this invention;

FIG. 4 (A), (B) is a perspective view illustrating the expansion unit of a fourth embodiment according to this invention;

FIG. 5 is a cross-sectional of an embodiment of an apparatus according to this invention;

FIG. 6 (A), (B) is a side view showing the expansion unit;

FIG. 7 is a side view illustrating a catheter;

FIG. 8 is a side view showing a catheter sheath;

FIG. 9 (A) to (E) is a schematic illustration showing the expansion unit in processes of inserting and withdrawing; and

FIG. 10 is a schematic illustration showing the expansion unit in another process of inserting and withdrawing.

An expansion unit 10 (hereinafter referred to as a stent) is substantially cylindrically (coil-like in this embodment) formed by a bidirectional shape memory alloy the size of which changes diametrically in accordance with changes in temperature. The measurement of the stent 10 in its matrix is set to a smaller size than that of a tubular organ, in this embodiment a blood vessel 11 (Refer to FIG. 1(A)). The stent 10 is further expanded diametrically (Refer to FIG. 1(B)).

The distal end portion of the cylindrical stent 10 is a high contrast portion 10a. The high contrast portion 10a is formed by the plating or pressing metals with a higher density (for example, Cu, Ag, Pt and Au) than the shape memory alloy comprising the stent 10. The high contrast portion may be at the rear end of, or at the center of, or at any two points of the stent 10, or the whole body of the cylindrical stent 10.

Thus, the stent 10 inserted into the inside of the blood vessel 11 definitely provides contrast under X-ray and can be indwelt into a desired location.

As regards the shape memory properties in accordance with the present invention, the shape memory alloy used in the present invention is a bidirectional shape memory alloy, in which two reversible memory shapes, i.e., high and low temperature sides, appear reversibly on the borderline of a certain transformation point, which is expanded diametrically to obtain the inside diameter of a blood vessel and the like at around body temperature, and which is capable of travelling inside of the blood vessel by being contracted diametrically at or below body temperature.

As regards the shape of the stent 10 according to this invention, other than the coil-like stent 10 of the first embodiment, substantially cylindrical things are included. "Substantially cylindrical things" in this invention mean things which have a surface contacting with at least part of a lumen for expanding and maintaining the lumen of a tubular organ.

A stent 40, according to a second embodiment, is constructed in a helical shape in cross section so as to contract (FIG. 2 (A)), or expand (FIG. 2 (B)). Numeral 40a indicates a high contrast portion.

A stent 50, with a l ngitudinal slit, according to a third embodiment, is cylindrically constructed so as to contract (FIG. 3 (A)) or expand (FIG. 3 (B)). Numeral 50a indicates a high contrast portion.

A stent 60, according to a fourth embodiment, is constructed in a mesh-like manner so as to contract (FIG. 4 (A)), or expand (FIG. 4 (B)). It is desirable that the distal end portion of the mesh be fixed by means of welding or an adhesive so that the thin wires of the shape memory alloy do not come loose. It is further desirable that the intersections comprising the thin wires of the alloy be fixed by means of welding or an adhesive. Numeral 60a indicates a high contrast portion.

The effects of the embodiments in accordance with this invention will now be specifically described.

The same shape stent, as shown in FIG. 1 (A), (B), made of Ti-Ni binary allow (including Ni atomic percent approximately 51), with a wall thickness of 0.004 mm, a width of 1 mm, is washed off with water after an electrolytic degreasing and an acid treatment, and plated with Au in the solution of $KAu(CN)_2$. When the already plated stent, and another stent not yet plated, are contrasted by X-rays under the same condition, the plated stent proves to provide improved contrast.

For proof of the improvement in contrast of the Au plating, the stent with Au plating and the stent not yet plated are exposed by X-rays under the condition of 45 kV and 2.0 mA, and a contrast picture is obtained. The absorbance of 600 nm of the picture is then obtained by a Shimazu second wavelength chromato scanner made by Shimazu Corp. In the spectrum thus obtained, let the contrast of the complete transmission of X-rays be 0, and the section where plating is not yet performed 1, then the Au plated stent becomes 3. A remarkable improvement in contrast by Au plating is proved.

An expansion system 101 is constructed in a combination of the expansion unit (stent) 110, the catheter 120 and the catheter sheath 130.

As shown in FIG. 6 (A), (B), the stent 110 is molded substantially, in a cylindrical and spiral manner, by a thin wire of a flat bidirectional shape memory alloy (made of, for example, Ni-Ti binary, Cu-Aℓ-Ni ternary, Cu-Zn-Aℓ ternary). The stent 110 is kept expanded diametrically in its shaped at around body temperature (for example, 30 - 35 °C) (FIG. 6 (B)), and is contracted diametrically in its shape substantially below body temperature (for example, 15 - 25°C) (FIG. 6 (A)). In the stent (Ti-Ni binary bidirectional shape memory alloy: Ni atomic percent about 51, a wall thickness of 0.03 mm, a width of 1 mm), the inside measurement thereof changes to Ø1.6mm at or under 20 °C, and to Ø2.8mm at or over 32 °C.

The inside diameter, length, etc. of the stent 110 may be appropriately determined by the inside diameter and the length of a tubular organ where the stent is to rest. That is, the inside diameter of the stent 110 is made equal to that of the tubular organ, such as a blood vessel, wh re th stent is to rest, when it is expanded, and is made small enough for the stent to be guided to a location where the stent is indwelt.

In this embodiment, the shape of the stent is not limited to the spiral shape described, but may be substantially cylindrically formed, such as for example, in a mesh-like or a helical shape.

Furthermore, it is desirable that the stent 110 be provided with an X-ray non-transmission marker 111 on at least part of the cylindrical body thereof.

The catheter 120 comprises a catheter tube 121 (made of thermoplastic resins, such as polyethylene, EVA or PVC) and a hollow hub 122 (made of, for example, polycarbonate or polyethylene) at the base of the catheter tube 121 to communicate with a lumen extending from the base of the catheter tube 121 to the distal end portion thereof. The catheter 120 allows the provision of the above-mentioned stent 110 on the periphery of a stent-attaching portion 123 close to the distal end portion of the catheter tube 121.

The catheter 120 also provides a passageway 124 between the lumen in the catheter tube 121 and the inside of the hub 122. The stent-attaching portion 123 of the catheter tube 121 is provided with a large number of side pores-like communication apertures 125 for communicating between the passageway 124 and the outside. The stent cooling water fed to the passageway 124 is discharged radially from the communication apertures 125. The communication apertures may also be slit-like.

It is further desirable that the catheter 120 be provided with an expansion 126, on the base portion of the stent-attaching portion 123 where the communication apertures 125 are located, and which has an outside measurement larger than that of the stent 110 attached to the stent-attaching portion 123. The reason for the above arrangement is that when the stent 110 is withdrawn, it is pulled inside the catheter sheath 130 while being wound around the stent-attaching portion 123. This prevents the catheter from being caught at the distal end portion of the catheter sheath 130. The expansion 126 may be arranged on both the base side and the distal end portion side of the stent attaching portion 123.

Moreover, it is desirable that the catheter 120 be provided with an X-ray non-transmission marker 127 (made of, for instance, gold or platinum) at a location in the vicinity of the distal end portion of the catheter tube 121. The marker permits confirmation of the location of the catheter 120 under x-ray fluoroscopy and the relative locations of the stent 110 and the sheath 130.

As shown in FIG. 7, the hub 122 of the catheter 120 comprises a linear cylindrical body 122A and a branch 122B branched at the center of the body 122A. The linear cylindrical body 122A serves as an entrance for the guide wire. A check valve 128 (made of a flexible mate-

rial, such as silicone rubber) is arranged close to the opening of the base of the body to prevent blood leakage and the like caused by the guide wire. The branch 122B, equipped with a three-way cock 129, is utilized for introducing cooling water and the like.

The catheter sheath 130 comprises a catheter tube 131, with both distal end portions opened, (made of, for example, PVC, polyethylene and fluorocarbon resin) and a hollow sheath hub 132 (made of, for example, polycarbonate or polyethylene) at the base of the catheter tube 131 to communicate with the lumen of the catheter tube 131. The catheter 120 with the stent 110 attached may be attached on the lumen of the catheter sheath 130.

The catheter sheath 130 must be flexible to travel through any bends in the periphery of a blood vessel, with the stent 110 and the catheter 120 sheathed into it. For this purpose, as the sheath 130 may be made of polyvinyl chloride, 15 - 40 parts by weight, preferably 20 - 30 of diethylhexylphthalate (DEHP) as a plasticizer are desirably contained for 100 parts by weight of polyvinyl chloride.

The catheter sheath 130 may desirably include the catheter tube 131, in whose material an X-ray contrast medium is so mixed as to confirm the location of each component under X-ray transmission. The catheter sheath 130 may also be provided with at least one X-ray non-transmission marker in the vicinity of the distal end portion of the sheath tube 131.

It is also desirable that the inside diameter of the sheath tube 131 of the catheter sheath 130 be smaller than the diameter of the stent 110 when it is expanded. This is because when the stent 110 is inserted by means of a combination of the stent 110, the catheter 120 and the sheath 130, the stent 110 is fixed to the inside of the sheath 130 due to the fact that the stent 110 tends to expand to a size larger than the inside diameter of the sheath. For the above-described reason, when the stent 110 is inserted by means of the combination of the stent 110, the catheter 120 and the sheath 130, into a location close to the indwelling location, the cooling water must not flow to wind the stent 110 around the catheter 120. Thus, firm insertion of the stent is achieved. Patient's discomfort will be greatly reduced by the small amount of cooling water required.

The sheath hub 132 of the catheter sheath 130 is provided with a check valve 133 for preventing blood from leaking when moving the catheter 120 within sheath lumen. The sheath hub 132 is further provided with a sheath port 134 for injection of a contrast medium and the like.

The effect of the above-mentioned embodiment will now be described.

The expansion system 101 hitherto described comprises the stent 110 made of the bidirectional shape memory alloy, where the outside diameter of the stent, smaller than the inside diameter of the lumen of the tubular organ within which the stent is to rest, is memorized when the temperature in the system is substantially below body temperature. Moreover, the stent 110 expands at around body temperature, and memorizes its outside diameter, equal to or somewhat larger than the inside diameter of the lumen of the tubular organ where the stent is to rest. The stent 110 is sheathed into the catheter sheath 130, while it is attached to the catheter 120. The stent 110 is readily indwelt in and withdrawn from a desired location of the tubular organ by inserting the above combination into the location.

That is, a guide wire is inserted by a known technique into the tubular organ where the stent is to rest, then, along the guide wire, the stent 110 is readily inserted into the desired location by using the above combination (Refer to FIG. 9(A)).

As shown in FIG. 9(A), instead of introducing directly a combination of the stent 110, the catheter 120 and the catheter sheath 130 into the tubular organ 11, it may be acceptable that, as shown in FIG. 10, the above combination is first introduced to the inside of the guiding catheter 200, which is already indwelt in the tubular organ 11, and then inserted into the tubular organ 11. However, the guiding catheter 200 can hardly pass through a bend in the periphery of the blood vessel because of its relative stiffness. This means that it is difficult for the guiding catheter 200 to be indwelt beforehand in the desired location of the tubular organ 11. Therefore, when the desired location is farther away from the indwelling location of the guiding catheter 200, the combination of the stent 110, the catheter 120 and the catheter sheath 130 is directly inserted into the tubular organ 11, after the combination passes the end of the location where the guiding catheter is indwelt.

According to this invention, at this time, since the stent 110 is firmly maintained within the catheter 120 thanks to the catheter sheath 130, while it is attached to the catheter 120, a large amount of cooling water need not be fed to keep the stent reduced in size, as when winding the stent around the catheter 120 tightly. This will reduce the patient's discomfort. Moreover, because of the catheter sheath 130, the stent 110 is not directly exposed to the guiding catheter 200 or the tubular organ 11, and is prevented from being caught or deformed midway through.

The stent 110 thus inserted into the desired location is projected out of the catheter sheath 130 (FIG. 9(C)), while it is wound around the catheter 120 (FIG. 9(B)) by the cooling water fed from the catheter sheath 130 and/or the communication apertures 125 of the catheter 120. After the stent 110 is thus projected (FIG. 9(C)), the supply of the cooling water is stopped. The stent 110 is heated by body temperature, and is expanded (FIG. 9(D)) to indwell in the desired location of the tubular organ (FIG. 9(E)).

Further, for withdrawing the stent thus indwelt in the desired location, the guide wire is passed the location where the stent 110 is indwelt, and along the guide wire, the combination of the catheter 120 and the catheter sheath 130 is inserted into the location. The distal end portion of the catheter 120 is then projected out of th

catheter sheath 130. The stent 110 is reduced in size by the cooling water fed from the catheter sheath 130 and/or the communication apertures 125 of the catheter 120 and is wound around th stent attaching porti n of the catheter 120. The wound stent 110 can be withdrawn by being pulled into the catheter sheath 130 together with the catheter 120. In this case too, only a small amount of the cooling water is required. The stent 110 after being pulled into the catheter sheath 130 can be definitely withdrawn without being caught or deformed midway through.

[Example 1]

A stent made of bidirectional shape memory alloy was indwelt and withdrawn, using the following materials.

The material of the stent was Ti-Ni binary alloy (approximately 51 percent Ni atoms), and the shape of the stent (wall thickness: t = 0.03 mm, width: w = 1 mm) was formed into a spiral, as shown in FIG. 1. The stent was changed in its diameter, to Ø1.6 mm at or under 20 °C, and to Ø2.8 mm at or over 32°C. Two gold markers (wall thickness t = 0.02 mm, w = 1.0 mm) were fixed to the both ends of the stent.

The material of the catheter was a blend of polyethylene and EVA, and the shape of the catheter was as shown in FIG. 5.

The material composition of the catheter sheath was 100 parts by weight of polyvinyl chloride, 50 parts by weight of Bi_2O_3 and 26 parts by weight of diethylhexylphthalate, and the shape of the sheath (outside diameter 3.0 mm, inside diameter 2.6 mm and wall thickness 0.2 mm) was as shown in FIG. 5.

The stent was indwelt and withdrawn in accordance with the following procedures.

① 80 mg of aspirin and 50 mg of dipyridamol were orally administered to a mongrel dog (17 kg) one day prior to an operation and again on the day of the operation.

② Under general anesthesia, the dog was heparinized (200 U/kg) after an introducer was indwelt by a know technique in an arteria femoralis.

③ A replacing guide wire was inserted by a known technique into a chosen blood vessel. A right arteria cervicalis superficialis was chosen in this case.

④ The combination of the stent, the catheter and the sheath (Refer to FIG. 1) was inserted, along the guide wire, into a location just before the indwelling location.

⑤ 30 mℓ per minute of the cooling water (ice-cooled physiological salt solution) was fed from the catheter side pores (communication apertures) to contract the stent.

⑥ The catheter was pushed out of the sheath to move it to the location where the catheter was to be indwelt. The feeding of the cooling water was stopped to expand and indwell the stent, and then the catheter sheath was withdrawn.

⑦ Thirty minutes later, along the guide wire, th combination of the catheter and the sheath was inserted into a location just before the indwelling location and then the catheter alone was inserted farther into the indwelling location, followed by the feeding of the cooling water.

⑧ After it was confirmed that the stent was wound around the catheter, the catheter together with the stent was pulled into the sheath. The feeding of the cooling water was then stopped and the stent together with the sheath was pulled out of the dog's body, thus completing the withdrawal operation.

The above procedures, from ③ to ⑧, were performed by using X-ray transmission.

By the above-mentioned procedures, it has been proved that indwelling and withdrawing of the stent can be easily performed.

[Example 2]

Before a stent, which had the same composition as the first example, with a spiral shape (wall thickness : t = 0.015 mm, width : w = 1.0mm), as shown in FIG. 1, and a diameter changed to Ø 1.4 mm with a temperature at or under 20 °C, and to Ø 2.8 mm with a temperature at or over 32 °C, was inserted or withdrawn, a guiding catheter was indwelt. The above combination was guided by the guiding catheter.

The material of the guiding catheter was made of polyurethane, and the outside diameter of the catheter was Ø 3.0 mm and the inside diameter Ø2.4 mm.

The material of the catheter sheath was the same as in the first embodiment, and the outside diameter of the sheath was Ø 2.0 mm and the inside diameter Ø1.8 mm.

The material of the catheter was a blend of polyethylene and EVA, and the shape was as shown in FIG. 5.

The combination of the guiding catheter, the stent, the catheter and the catheter sheath was firmly guided by the guiding catheter to a point in the blood vessel which was midway to the desired location. The combination was directly inserted into the blood vessel after travelling through the end where the guiding catheter was indwelt. As a result, it was proved that the stent could be easily indwelt and withdrawn.

An expansion unit according to the present invention is utilized for maintaining the inside measurements of the lumen of such tubular organ as, for example, a blood vessel, a digestive tube or an air tube so as to prevent a coronary artery from relapsing into a constricted state after it has been dilated and indwelt by an angiectasia catheter.

An apparatus according to this invention is used for indwelling and withdrawing the aforementioned expansion unit.

Claims

1. A tubular-organ expansion apparatus for indwelling a tubular expansion unit in a lumen of a tubular body organ comprising the combination of:

   - a tubular-organ expansion unit (110) consisting of a cylindrical body of a given contrast made of a bidirectional shape memory alloy having a given density which is insertable into a tubular body organ and capable of maintaining an inside diameter of a lumen of the tubular body organ, said cylindrical body being capable of reversibly achieve an unexpanded state of a given radial dimension and outside diameter in a first temperature range below body temperature and an expanded state of an increased given radial dimension and outside diameter in a second temperature range around body temperature;
   - a catheter (120) including a base portion having an outside diameter, a distal end portion having an outside diameter, an outside portion having an outside diameter and a tubular-organ expansion unit attaching portion (123) having a periphery in the vicinity of said distal end portion for attaching said tubular-organ expansion unit (110) to said catheter; and
   - a catheter sheath (130) having first and second open end portions sheathing said tubular-organ expansion unit when said tubular-organ expansion unit is attached to said tubular organ-expansion unit attaching portion, said catheter sheath comprising a flexible catheter tube (131) having an inside diameter smaller than that of the outside diameter of the tubular-organ expansion unit in its expanded state but larger than the outside diameter of the tubular-organ expansion unit in its unexpanded state, said tubular-organ expansion unit being fixed to the inside of said sheath when the combination of said tubular-organ expansion unit, said catheter and said sheath is held at a temperature within said second temperature range so that said combination can be introduced as a whole in the vicinity of the indwelling location of said tubular expansion unit.

2. A tubular-organ expansion apparatus according to claim 1, wherein said catheter further comprises:

   a passageway (124) extending from said base portion to at least a location in the vicinity of said distal end portion; and
   at least one of side pores or slit-like communication apertures (125) for providing fluid communication between said passageway (124) and said outside portion.

3. A tubular-organ expansion apparatus according t claim 2, wherein at least one of the outside diameter of said base portion and th outside diameter of said distal end portion is larger than th outsid diameter of said tubular-organ expansion unit (110) attached to said tubular-organ expansion unit attaching portion (123) when said tubular-organ expansion unit is in an unexpanded state.

4. A tubular-organ expansion apparatus according to claim 3, wherein said catheter (120) further comprises:

   a catheter lumen extending from said base portion to at least a location in the vicinity of said distal end portion; and
   a hollow hub (122) having a hub lumen therein provided on said base portion for communicating with said catheter lumen; and
   said passageway (124) being defined by said catheter lumen and said hub lumen.

5. A tubular-organ expansion apparatus according to claim 4, wherein said hollow hub (122) comprises:

   a branch hub having two ports (122A, 122B); and
   a check valve (128) provided on one of said two ports.

6. A tubular-organ expansion apparatus according to anyone of claims 1 to 5, wherein said catheter is provided with at least one X-ray non-transmission marker (127) in the vicinity of said distal end portion.

7. A tubular-organ expansion apparatus according to anyone of claims 1 to 6, wherein said catheter sheath (130) includes at least one of:

   an X-ray non-transmission material mixed in the material of said catheter sheath (130); and
   at least one X-ray non-transmission marker in the vicinity of said distal end portion.

8. A tubular-organ apparatus according to anyone of claims 1 to 7, wherein said catheter sheath (130) comprises:

   a sheath lumen extending between the first and second open end portions thereof;
   a hollow hub (132) including a hub lumen on said base portion; and
   a check valve (133) positioned in said hollow hub for controlling fluid communicating between said sheath lumen and said hub lumen.

9. A tubular-organ apparatus according to anyone of

claims 1 to 8, wherein both the outside diameter of said base portion of said catheter (120) and the outside diameter of said tubular-organ expansion unit attaching portion (123) in th vicinity of said distal end portion of said catheter (120) are substantially equal in diameter to each other and both said outside diameters are at least equal in size to the inside diameter of said tubular-organ expansion unit (110) when said tubular-organ expansion unit is in the unexpanded state so that said tubular-organ expansion unit attaching portion (123) is capable of having said tubular-organ expansion unit (110) attached thereto at a temperature within said first temperature range.

10. A tubular-organ expansion apparatus as in anyone of the preceding claims wherein said tubular-organ expansion unit is selected from the group comprising a coil-like cylindrical body, a cylindrical body having a helical shape in cross-section, a cylindrical body slitted lengthwise, and a mesh-like cylindrical body.

11. A tubular-organ expansion apparatus as in claim 10, wherein the tubular-organ expansion unit is a mesh-like cylindrical body defined by thin woven-shaped wires of shape memory alloy.

12. A tubular-organ expansion apparatus as in anyone of claims 1 to 11, further comprising X-ray contrast enhancing means on at least a portion (10a) of said cylindrical body (10) of said tubular-organ expansion unit for improving the X-ray contrast of at least said portion of said cylindrical body relative to said given X-ray contrast.

13. A tubular-organ expansion apparatus according to claim 12, wherein said X-ray contrast enhancing means comprises a metal plated on at least said portion of said cylindrical body, said plated metal having a density higher than said given density of said shape memory alloy.

14. A tubular-organ expansion apparatus according to claim 12, wherein said X-ray contrast enhancing means comprises a metal pressed on at least said portion of said cylindrical body, said pressed metal having a density higher than said given density of said shape memory alloy.

Patentansprüche

1. Aufweitvorrichtung für schlauchförmige Organe für das Verweilen einer schlauchförmigen Aufweiteinheit in einem Lumen eines schlauchförmigen Körperorgans, umfassend die Kombination:

- einer Aufweiteinheit für schlauchförmige Organe (110), bestehend aus einem Zylinderkörper mit einem vorgegebenen Kontrast, der aus einer eine vorgegebene Dichte aufweisend n bidirektionalen Formgedächtnislegierung h rgestellt ist, die in ein schlauchförmiges Körperorgan einführbar ist und in der Lage ist, einen Innendurchmesser eines Lumens des schlauchförmigen Körperorgans aufrechtzuerhalten, wobei der zylindrische Körper in der Lage ist, umkehrbar einen nichtaufgeweiteten Zustand mit einer vorgegebenen radialen Abmessung und einem Außendurchmesser in einem ersten Temperaturbereich unterhalb der Körpertemperatur und einen aufgeweiteten Zustand mit einer vergrößerten vorgegebenen radialen Abmessung und einem Außendurchmesser in einem zweiten Temperaturbereich um Körpertemperatur herum zu erreichen;
- eines Katheters (120), umfassend einen Basisabschnitt, der einen Außendurchmesser aufweist, einen distalen Endabschnitt, der einen Außendurchmesser aufweist, einen Außenabschnitt, der einen Außendurchmesser aufweist, und einen Befestigungsabschnitt der Aufweiteinheit für schlauchförmige Organe, der einen Umfang in der Nähe des distalen Endabschnitts aufweist, um die Aufweiteinheit für schlauchförmige Organe (110) am Katheter zu befestigen; und
- eines Kathetergehäuses (130), das einen ersten und einen zweiten offenen Endabschnitt aufweist, umhüllend die Aufweiteinheit für schlauchförmige Organe, wenn die Aufweiteinheit für schlauchförmige Organe am Befestigungsabschnitt der Aufweiteinheit für schlauchförmige Organe angebracht ist, wobei das Kathetergehäuse einen flexiblen Katheterschlauch (131) umfaßt, der einen Innendurchmesser aufweist, der kleiner als der Außendurchmesser der Aufweiteinheit für schlauchförmige Organe in ihrem aufgeweiteten Zustand, aber größer als der Außendurchmesser der Aufweiteinheit für schlauchförmige Organe in ihrem nicht aufgeweiteten Zustand ist, wobei die Aufweiteinheit für schlauchförmige Organe im Inneren des Gehäuses befestigt ist, wenn die Kombination der Aufweiteinheit für schlauchförmige Organe, des Katheters und des Gehäuses bei einer Temperatur innerhalb des zweiten Temeraturbereichs gehalten wird, so daß die Kombination als Ganzes in die Nähe der Verweilstelle der schlauchförmigen Aufweiteinheit eingeführt werden kann.

2. Aufweitvorrichtung für schlauchförmige Organe nach Anspruch 1, bei der der Katheter weiter umfaßt:

einen Durchgang (124), der sich vom Basisab-

schnitt bis zu wenigstens einer Stelle in der Nähe des distalen Endabschnitts erstreckt; und wenigstens eines von Seitenporen oder schlitzartigen Verbindungsöffnungen (125), um Fluidverbindung zwischen dem Durchgang (124) und dem Außenabschnitt vorzusehen.

3. Aufweitvorrichtung für schlauchförmige Organe nach Anspruch 2, bei der wenigstens einer von dem Außendurchmesser des Basisabschnitts und dem Außendurchmesser des distalen Endabschnitts größer als der Außendurchmesser der an den Befestigungsabschnitt der Aufweiteinheit für schlauchförmige Organe (123) angebrachten Aufweiteinheit für schlauchförmige Organe (110) ist, wenn sich die Aufweiteinheit für schlauchförmige Organe in einem nicht aufgeweiteten Zustand befindet.

4. Aufweitvorrichtung für schlauchförmige Organe nach Anspruch 3, bei der der Katheter (120) weiter umfaßt:

   ein Katheterlumen, das sich vom Basisabschnitt bis zu wenigstens einer Stelle in der Nähe des distalen Endabschnitts erstreckt; und
   ein Hohlnabenelement (122), das ein darin am Basisabschnitt vorgesehenes Nabenelementlumen aufweist, um mit dem Katheterlumen verbunden zu sein; und
   wobei der Durchgang (124) durch das Katheterlumen und das Nabenelementlumen gebildet wird.

5. Aufweitvorrichtung für schlauchförmige Organe nach Anspruch 4, bei der das Hohlnabenelement (122) umfaßt:

   ein Zweignabenelement, das zwei Öffnungen (122A, 122B) aufweist; und
   ein Rückschlagventil (128), das an einer der beiden Öffnungen vorgesehen ist.

6. Aufweitvorrichtung für schlauchförmige Organe nach einem der Ansprüche 1 bis 5, bei der der Katheter mit wenigstens einer röntgenstrahlenundurchlässigen Markierung (127) in der Nähe des distalen Endabschnitts versehen ist.

7. Aufweitvorrichtung für schlauchförmige Organe nach einem der Ansprüche 1 bis 6, bei der das Kathetergehäuse (130) wenigstens eines umfaßt von:

   einem röntgenstrahlenundurchlässigen Material, vermischt mit dem Material des Kathetergehäuses (130); und
   wenigstens einer röntgenstrahlenundurchlässigen Markierung in der Nähe des distalen Endabschnitts.

8. Vorrichtung für schlauchförmige Organe nach einem der Ansprüche 1 bis 7, bei der das Kathetergehäuse (130) umfaßt:

   ein Gehäuselumen, das sich zwischen seinen ersten und zweiten offenen Endabschnitten erstreckt;
   ein Hohlnabenelement (132), das ein Nabenelementlumen am Basisabschnitt umfaßt; und
   ein Rückschlagventil (133), das im Hohlnabenelement angeordnet ist, um die Fluidverbindung zwischen dem Gehäuselumen und dem Nabenelementlumen zu kontrollieren.

9. Vorrichtung für schlauchförmige Organe nach einem der Ansprüche 1 bis 8, bei der der Außendurchmesser des Basisabschnitts des Katheters (120) und der Außendurchmesser des Befestigungsabschnitts der Aufweiteinheit für schlauchförmige Organe (123) in der Nähe des distalen Endabschnitts des Katheters (120) im wesentlichen beide im Durchmesser gleich sind und beide Außendurchmesser wenigstens die gleiche Größe wie der Innendurchmesser der Aufweiteinheit für schlauchförmige Organe (110) haben, wenn sich die Aufweiteinheit für schlauchförmige Organe im nicht aufgeweiteten Zustand befindet, so daß es möglich ist, daß die Aufweiteinheit für schlauchförmige Organe (110) bei einer Temperatur innerhalb des ersten Temperaturbereichs an dem Befestigungsabschnitt der Aufweiteinheit für schlauchförmige Organe (123) befestigt ist.

10. Aufweitvorrichtung für schlauchförmige Organe nach einem der vorhergehenden Ansprüche, bei der die Aufweiteinheit für schlauchförmige Organe aus einer Gruppe ausgewählt ist, die einen spulenartigen Zylinderkörper, einen einen spiralförmigen Querschnitt aufweisenden Zylinderkörper, einen längsgeschlitzten Zylinderkörper und einen maschenartigen Zylinderkörper umfaßt.

11. Aufweitvorrichtung für schlauchartige Organe nach Anspruch 10, bei der die Aufweiteinheit für schlauchförmige Organe ein maschenartiger Zylinderkörper ist, der durch dünne gewebeförmige Drähte aus Formgedächtnislegierung umgrenzt ist.

12. Aufweitvorrichtung für schlauchförmige Organe nach einem der Ansprüche 1 bis 11, weiter umfassend Röntgenstrahlkontrasterhöhungsmittel an wenigstens einem Abschnitt (10a) des Zylinderkörpers (10) der Aufweiteinheit für schlauchförmige Organe, um den Röntgenstrahlenkontrast von wenigstens dem Abschnitt des Zylinderkörpers in bezug auf den vorgegebenen Röntgenstrahlenkontrast zu verbessern.

13. Aufweitvorrichtung für schlauchförmige Organe nach Anspruch 12, bei der das Röntgenstrahlkontrasterhöhungsmittel ein wenigstens auf dem Abschnitt des Zylinderkörpers plattiertes Metall umfaßt, wobei das plattiert Metall eine höhere Dichte als die vorgegebene Dichte der Formgedächtnislegierung aufweist.

14. Aufweitvorrichtung für schlauchförmige Organe nach Anspruch 12, bei der das Röntgenstrahlkontrasterhöhungsmittel ein auf wenigstens den Abschnitt des Zylinderkörpers gepreßtes Metall umfaßt, wobei das gepreßte Metall eine höhere Dichte als die vorgegebene Dichte der Formgedächtnislegierung aufweist.

Revendications

1. Dispositif de dilatation d'un organe tubulaire servant à implanter une unité tubulaire de dilatation dans la lumière d'un organe tubulaire du corps, comprenant en association :

- une unité (110) de dilatation d'organe tubulaire comprenant un corps cylindrique de contraste donné, fait en un alliage à mémoire de forme bidirectionnelle ayant une densité donnée, qui peut être introduit dans un organe tubulaire du corps et qui peut maintenir le diamètre intérieur de la lumière de l'organe tubulaire du corps, ledit corps cylindrique pouvant prendre de manière réversible un état contracté correspondant à une dimension radiale et un diamètre extérieur donnés dans une première plage de températures inférieures à la température du corps, et un état dilaté correspondant à une dimension radiale et un diamètre extérieur donnés, plus grands, dans une seconde plage de températures situées autour de la température du corps,
- un cathéter (120) comprenant une partie de base avec un certain diamètre extérieur, une partie d'extrémité distale avec un certain diamètre extérieur, une partie extérieure avec un certain diamètre extérieur et une partie (123) de fixation de l'unité de dilatation de l'organe tubulaire dont la périphérie, proche de ladite partie d'extrémité distale, sert à fixer ladite unité (110) de dilatation d'organe tubulaire audit cathéter, et
- une gaine de cathéter (130), ayant une première et une seconde parties d'extrémité ouvertes, qui protège ladite unité de dilatation d'organe tubulaire quand ladite unité de dilatation d'organe tubulaire est fixée à ladite partie de fixation de l'unité de dilatation de l'organe tubulaire, ladite gaine de cathéter comprenant un tube de cathéter flexible (131) qui a un diamètre intérieur plus petit que le diamètre e térieur de l'unité de dilatation d'organ tubulaire à l'état dilaté mais plus grand que le diamètre extérieur de l'unité de dilatation d'organe tubulaire à l'état contracté, ladite unité de dilatation d'organe tubulaire étant fixée à l'intérieur de ladite gaine quand l'association de ladite unité de dilatation d'organe tubulaire, dudit cathéter et de ladite gaine est maintenue à une température comprise dans ladite seconde plage de températures, de sorte que ladite association peut être introduite comme un tout au voisinage de l'emplacement d'implantation de ladite unité de dilatation d'organe tubulaire.

2. Dispositif de dilatation d'un organe tubulaire selon la revendication 1, dans lequel ledit cathéter comprend en outre :

- une voie de passage (124) qui part de ladite partie de base et s'étend au moins jusqu'à un emplacement proche de ladite partie d'extrémité distale, et
- des orifices latéraux de communication (125), en forme de pores ou de fentes, qui assurent la communication entre ladite voie de passage (124) et ladite partie extérieure.

3. Dispositif de dilatation d'un organe tubulaire selon la revendication 2, dans lequel l'un au moins du diamètre extérieur de ladite partie de base et du diamètre extérieur de ladite partie d'extrémité distale est plus grand que le diamètre extérieur de ladite unité (110) de dilatation d'organe tubulaire fixée à ladite partie (123) de fixation d'unité de dilatation d'organe tubulaire lorsque ladite unité de dilatation d'organe tubulaire est à l'état contracté.

4. Dispositif de dilatation d'un organe tubulaire selon la revendication 3, dans lequel ledit cathéter (120) comprend en outre :

- une lumière de cathéter qui part de ladite partie de base et s'étend au moins jusqu'à un emplacement proche de ladite partie d'extrémité distale, et
- un manchon creux (122) ayant une lumière de manchon, placé en ladite partie de base pour communiquer avec ladite lumière du cathéter,

ladite voie de passage (124) étant définie par ladite lumière du cathéter et ladite lumière du manchon.

5. Dispositif de dilatation d'un organe tubulaire selon la revendication 4, dans lequel ledit manchon creux (122) comprend :

- un manchon fourchu avec deux accès (122A, 122B), et
- un clapet anti-retour (128) placé sur l'un des-

dits deux accès.

6. Dispositif de dilatation d'un organe tubulaire selon l'une quelconque des revendications 1 à 5, dans lequel ledit cathéter comporte au moins un repère (127) ne transmettant pas les rayons X au voisinage de ladite partie d'extrémité distale.

7. Dispositif de dilatation d'un organe tubulaire selon l'une quelconque des revendications 1 à 6, dans lequel ladite gaine de cathéter (130) comprend au moins :

- soit un matériau ne transmettant pas les rayons X, mélangé dans le matériau de ladite gaine de cathéter (130),
- soit au moins un repère ne transmettant pas les rayons X, au voisinage de ladite partie d'extrémité distale.

8. Dispositif de dilatation d'un organe tubulaire selon l'une quelconque des revendications 1 à 7, dans lequel ladite gaine de cathéter (130) comprend :

- une lumière de gaine qui s'étend entre ses première et seconde parties d'extrémités,
- un manchon creux (132) avec une lumière de manchon sur ladite partie de base, et
- un clapet anti-retour (133) placé dans ledit manchon creux pour commander la communication des fluides entre ladite lumière de la gaine et ladite lumière du manchon.

9. Dispositif de dilatation d'un organe tubulaire selon l'une quelconque des revendications 1 à 8, dans lequel le diamètre extérieur de ladite partie de base dudit cathéter (120) et le diamètre extérieur de ladite partie (123) de fixation de l'unité de dilatation d'organe tubulaire proche de ladite partie d'extrémité distale dudit cathéter (120) sont sensiblement identiques entre eux et lesdits deux diamètres extérieurs sont au moins égaux au diamètre intérieur de ladite unité (110) de dilatation d'organe tubulaire quand ladite unité de dilatation d'organe tubulaire est à l'état contracté de sorte que ladite unité (110) de dilatation d'organe tubulaire peut être fixée à ladite partie (123) de fixation de l'unité de dilatation d'organe tubulaire à une température située dans ladite première plage de températures.

10. Dispositif de dilatation d'un organe tubulaire selon l'une quelconque des précédentes revendications, dans lequel ladite unité de dilatation d'organe tubulaire est choisie dans un groupe comprenant un corps cylindrique de forme hélicoïdale, un corps cylindrique ayant une section en forme de spirale, un corps cylindrique fendu dans le sens de la longueur et un corps cylindrique en forme de treillis.

11. Dispositif de dilatation d'un organe tubulaire selon la revendication 10, dans lequel ladite unité de dilatation d'organe tubulaire est un corps cylindriqu en forme de treillis formé par de minces fils en alliag à mémoire de forme tissés.

12. Dispositif de dilatation d'un organe tubulaire selon l'une quelconque des revendications 1 à 11, comprenant en outre un moyen d'amélioration du contraste aux rayons X sur une partie au moins (10a) dudit corps cylindrique (10) de ladite unité de dilatation d'organe tubulaire pour améliorer le contraste aux rayons X de ladite partie au moins dudit corps cylindrique par rapport audit contraste aux rayons X donné.

13. Dispositif de dilatation d'un organe tubulaire selon la revendication 12, dans lequel ledit moyen d'amélioration du contraste aux rayons X comprend un métal plaqué sur ladite partie au moins dudit corps cylindrique, ledit métal plaqué ayant une densité plus élevée que ladite densité donnée dudit alliage à mémoire de forme.

14. Dispositif de dilatation d'un organe tubulaire selon la revendication 12, dans lequel ledit moyen d'amélioration du contraste aux rayons X comprend un métal pressé sur ladite partie au moins dudit corps cylindrique, ledit métal pressé ayant une densité plus élevée que ladite densité donnée dudit alliage à mémoire de forme.

FIG. 1

(A) (B)

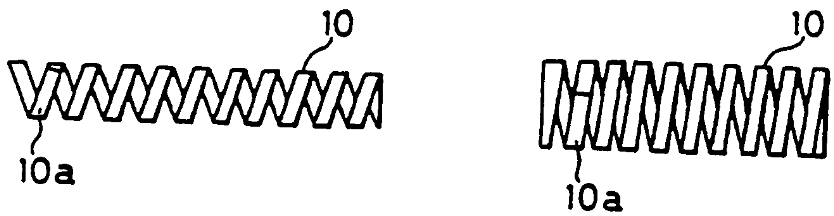

FIG. 2

(A) (B)

FIG.3

(A) (B)

FIG.4

(A) (B)

FIG.5

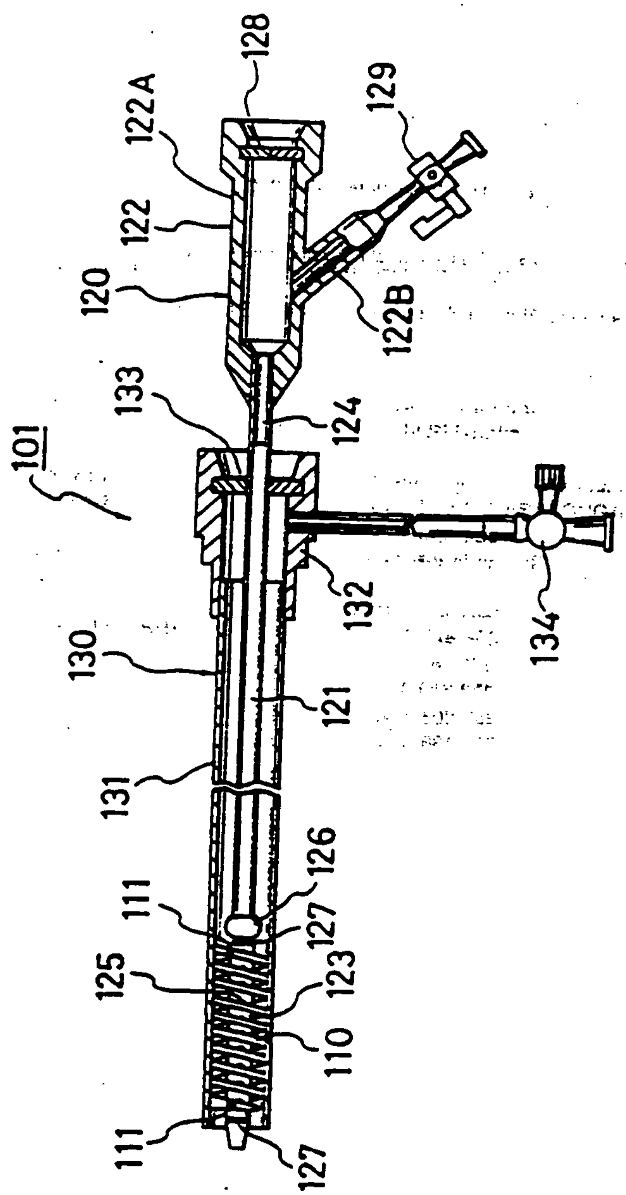
101
128
122A
129
122
120
122B
133
124
132
134
130
121
131
126
111
127
125
123
110
111
127

FIG.6

(A) (B)

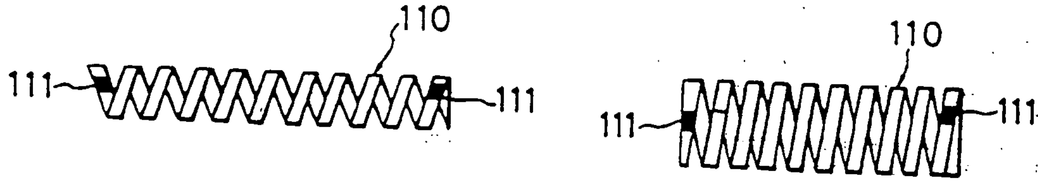

FIG. 7

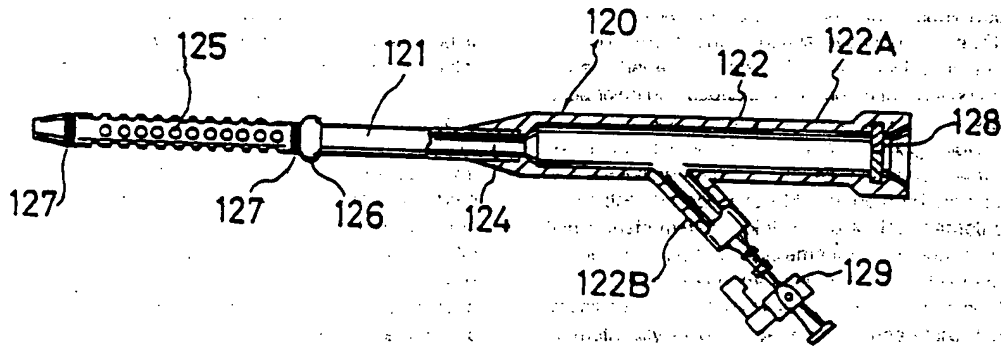

FIG.8

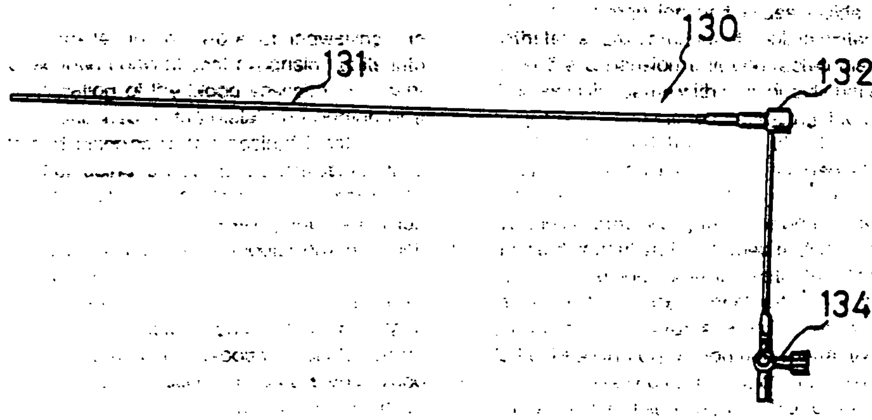

FIG. 9

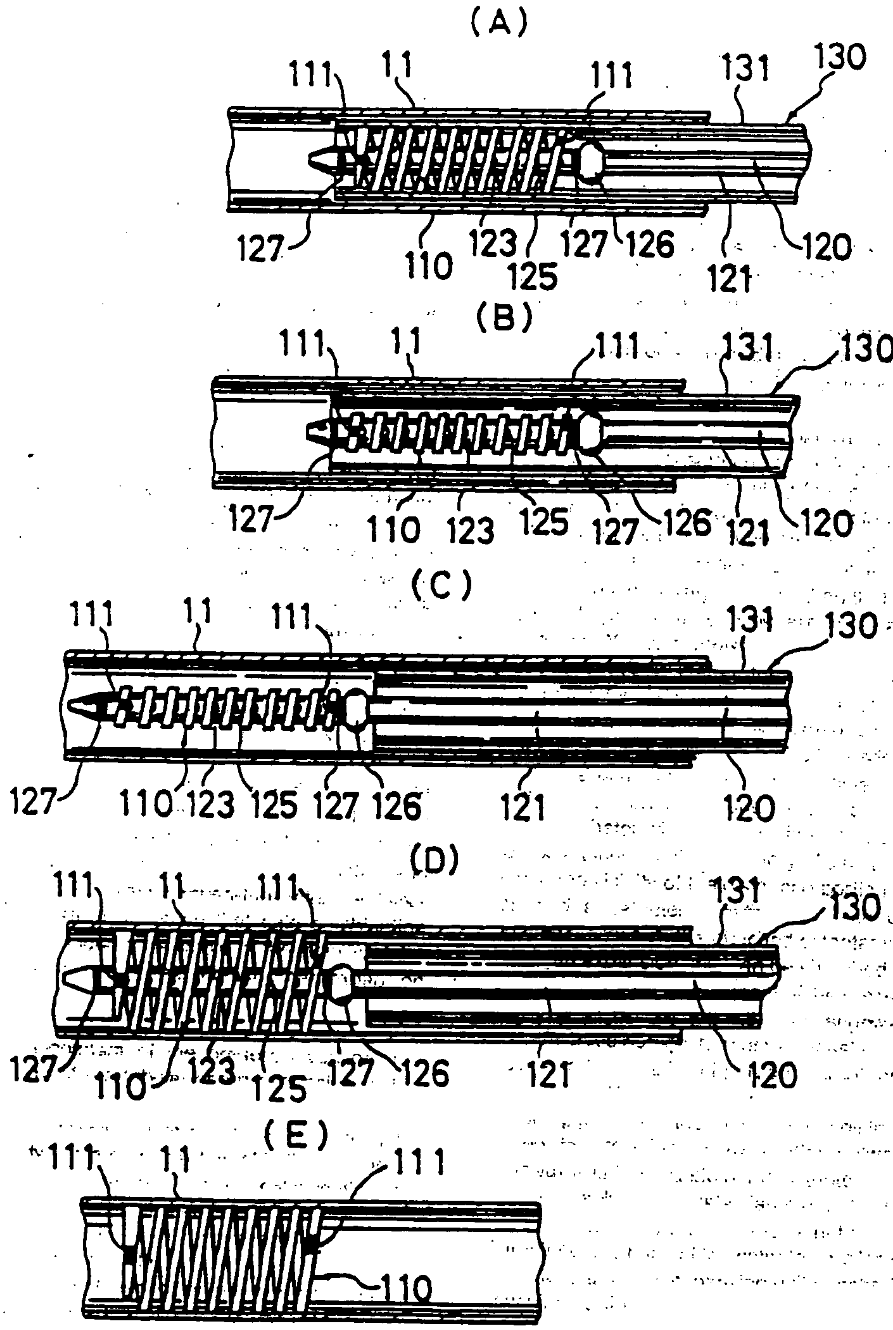
(A)
111
11
111
131
130
127
110
123
125
127
126
121
120
(B)
111
11
111
131
130
127
110
123
125
127
126
121
120
(C)
111
11
111
131
130
127
110
123
125
127
126
121
120
(D)
111
11
111
131
130
127
110
123
125
127
126
121
120
(E)
111
11
111
110

FIG. 10